



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2011-N-0003]

New Animal Drugs For Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for approval of free-choice feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95-735 that provides for use of RUMENSIN 90 (monensin) Type A medicated article in free-choice feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers) for increased rate of weight gain and for prevention and control of coccidiosis. The supplemental NADA is approved as of November 18, 2011, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

## PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. In § 558.355, add paragraph (f)(3)(iv); and in paragraph (f)(3)(x)(c), remove the last sentence.

The addition reads as follows:

§ 558.355 Monensin.

\* \* \* \* \*

(f) \* \* \*

(3) \* \* \*

(iv) Amount. Monensin at concentrations in free-choice Type C medicated feeds to provide 50 to 200 mg per head per day

(a) Indications for use. Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii.

(b) Limitations. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated supplement before using the monensin medicated supplement. The product's effectiveness in cull cows and bulls has not been established. See paragraph (d) of this section for other required label warnings.

\* \* \* \* \*

Dated: January 23, 2012.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

[FR Doc. 2012-1755 Filed 01/26/2012 at 8:45 am; Publication Date: 01/27/2012]